



U.S. Department of Health and Human Services

Food and Drug Administration



**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
MEDICAL DEVICES ADVISORY COMMITTEE
MEETING OF THE
DENTAL PRODUCTS PANEL**

Tuesday, 13 July 2004

**Hilton Washington DC North
Ballroom Salons A and B
Gaithersburg, Maryland**

BACKGROUND

BioMimetic Pharmaceuticals, Inc., of Franklin, Tennessee, submitted an original Premarket Approval Application (PMA) to the FDA on March 12, 2004, for a device called "GEM 21S." GEM 21S is a beta-tricalcium phosphate (β -TCP) bone void filler that is intended to be combined with Becaplermin, a wound-healing drug, to treat osseous defects resulting from periodontal disease, cystectomy, apicoectomy, deficient alveolar ridges, and tooth extraction. The sponsor states that the β -TCP component serves as a scaffold to guide the three dimensional regeneration of bone in a clinical defect site and that the Becaplermin component, which is added to the β -TCP scaffold, promotes cellular in-growth into the intra-osseous defect and scaffold and revascularization of the wound site.

In accordance with the procedures for review set forth in 21 CFR 814.44, FDA has referred the PMA to the Dental Products Panel of the Medical Devices Advisory Committee for the Panel's recommendation.

PANEL ACTION

At this meeting, the Dental Products Panel will discuss and/or vote on the following:

- ?? Whether the device is approvable, approvable with conditions, or not approvable, and
- ?? The basis for the recommendation above.



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MEETING AGENDA
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- 8:00 a.m. **CLOSED SESSION – Dental Devices Branch Updates**
This portion of the meeting is closed to public participation. The committee will discuss commercial information regarding future device applications.
- 8:30 a.m. **CALL TO ORDER**
- 8:30 - 8:45 a.m. **OPEN SESSION -- Welcome and Introductory Remarks**
?? Dr. Jon B. Suzuki, Chairman
?? Mr. Michael E. Adjodha, Executive Secretary
- 8:45 – 9:00 a.m. **Open Public Hearing**
Public attendees, who have contacted the Executive Secretary prior to the meeting, will address the Panel and present information relevant to the agenda. Speakers are asked to state whether or not they have any financial involvement with sponsor of the product(s) being discussed or with their competitors
- 9:00 - 10:30 a.m. **Presentation by the Sponsor – GEM 21S (P040013)**
?? Mr. Mark Citron
?? Dr. Samuel E. Lynch
?? Dr. William V. Giannobile
?? Dr. Myron Nevins
?? Dr. Robert Genco
- 10:30 - 10:45 a.m. **BREAK**

MEETING AGENDA continued

10:45 - 11:45 a.m.	Presentation by the FDA – GEM 21S (P040013) ?? Dr. M. Susan Runner, Chief, Dental Devices Branch and Deputy Director, DAGID ?? Ms. Angela E. Blackwell, Biomedical Engineer, Dental Devices Branch ?? Ms. Judy S. Chen, Statistician, Office of Surveillance and Biometrics
12:00 - 1:00 p.m.	LUNCH BREAK
1:00 - 2:45 p.m.	Panel Deliberations
2:45 - 3:00 p.m.	BREAK
3:00 - 3:30 p.m.	Open Public Session <i>This portion of the meeting is open to public observers. Public observers may not participate except at the specific request of the Chairperson.</i>
3:30 – 3:45 p.m.	Summation ?? FDA ?? Sponsor
3:45 - 4:45 p.m.	Panel Recommendation and Vote
5:00 p.m.	MEETING ADJOURNED

DENTAL PRODUCTS PANEL

Tuesday, 13 July 2004

CHAIR	EXECUTIVE SECRETARY
Jon B. Suzuki, DDS, PhD, MBA Professor University of Pittsburgh, School of Dental Medicine Pittsburgh, Pennsylvania	Michael E. Adjodha, MChE Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health Office of Device Evaluation Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGID)

PANEL MEMBERS AND CONSULTANTS

Name	Affiliation	Role
Salomon Amar, DDS, PhD	Professor, Periodontology Boston University, School of Dental Medicine Boston, Massachusetts	Voting Member
David L. Cochran, DDS, PhD	Professor and Chairman, Periodontology University of Texas, Health Science Center San Antonio, Texas	Voting Member Non-voting for this meeting
Elizabeth S. Howe	Outreach Coordinator National Foundation for Ectodermal Dysplasias Auburn, Washington	Consumer Representative Non-voting Member
Alison F. Lawton, MBA	Senior Vice President, Genzyme Corporation Cambridge, Massachusetts	Drug Industry Representative Non-voting Member
William J. O'Brien, MS, PhD	Professor, Materials Science University of Michigan, School of Dentistry Ann Arbor, Michigan	Voting Member Non-voting for this meeting
Daniel R. Schechter, JD	General Counsel Parkell, Incorporated Farmingdale, New York	Device Industry Representative Non-voting Member
Inder J. Sharma, PhD	Associate Professor, Biostatistics Morehouse School of Medicine, Department of Community Health and Preventative Medicine Atlanta, Georgia	Consultant Deputized to Vote
Domenick T. Zero, DDS, MS	Professor and Chairman, Preventative Dentistry Indiana University, School of Dentistry Indianapolis, Indiana	Voting Member
John R. Zuniga, PhD, DMD	Professor and Graduate Program Director, Oral Surgery University of North Carolina, School of Dentistry Chapel Hill, North Carolina	Voting Member

OTHER PARTICIPANTS

FDA
Chiu S. Lin, PhD Division Director, DAGID DHHS/FDA/CDRH/ODE
M. Susan Runner, DDS, MA, Captain, USPHS Deputy Division Director, DAGID and Chief, Dental Devices Branch DHHS/FDA/CDRH/ODE
Angela E. Blackwell, MS Biomedical Engineer Dental Devices Branch DHHS/FDA/CDRH/ODE
Robert S. Betz, DDS, Captain, USPHS Dental Officer Dental Devices Branch DHHS/FDA/CDRH/ODE
Judy S. Chen, MS Mathematical Statistician (Biomedical) Division of Biostatistics DHHS/FDA/CDRH/OSB
Janie G. Fuller, DDS, Captain, USPHS Dental Officer Division of Postmarket Surveillance DHHS/FDA/CDRH/OSB
Kurt Stromberg, MD Medical Officer Division of Therapeutic Proteins DHHS/FDA/CDER/OPS/OBP

SPONSOR
Mark Citron, Vice President, Regulatory Affairs BioMimetic Pharmaceuticals, Inc. Franklin, Tennessee
Samuel E. Lynch, DMD, DMSc President and CEO BioMimetic Pharmaceuticals, Inc.
William V. Giannoble, DDS, DMSc Associate Professor University of Michigan
Myron Nevins, DDS Associate Professor Harvard University
Robert Genco, DDS, PhD Vice Provost State University of New York at Buffalo

QUESTIONS FOR PANEL DISCUSSION

1. Considering the statistical results, is there a clinically significant benefit from the addition of rhPDGF-BB to β -TCP?
2. What impact does relying exclusively on secondary endpoints and retrospective analyses have on the validity of the clinical study?
3. Are the following intended uses for the device, proposed by the sponsor, supported by valid scientific evidence¹:
 - ?? periodontal disease,
 - ?? cystectomy,
 - ?? apicoectomy,
 - ?? deficient alveolar ridges, and
 - ?? tooth extraction?If not, which of these claims is not supported?
4. Does the information provided by the sponsor provide a reasonable assurance that the device is safe² under the conditions of use prescribed, recommended, or suggested in the proposed labeling? If not, what information is needed to establish the safety of this device for its intended use?
5. Does the information provided by the sponsor provide a reasonable assurance that the device is effective³ under the conditions of use prescribed, recommended, or suggested in the proposed labeling? If not, what information is needed to establish the effectiveness of this device for its intended use?

¹ Valid scientific evidence includes:

Well-Controlled Investigations
Partially Controlled Studies
Studies & Objective Trials without Matched Controls
Well-Documented Case Histories by Qualified Experts
Reports of Significant Human Experience with a Marketed Device

² There is a reasonable assurance that a device is **safe** when it can be determined, based upon valid scientific evidence, that the probable benefits to health from the use of the device for its intended uses and conditions for use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of the device shall adequately demonstrate the absence of unreasonable risk associated with the use of the device for its intended uses and conditions for use.

³ There is a reasonable assurance that a device is **effective** when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.